FDA Public Meeting
Re: WHO Scheduling Recommendations on Ephedrine
February 19, 1099

Written Comments of:
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The recommendations of the World Health Organization to Impose international manufacturing and distributing restrictions on certain ephedrine products by placing the 1-ephedrine stereoisomeric form of ephedrine and its corresponding racemic mixture d, 1 -ephedrine in Schedule IV of the Convention on Psychotropic Substances, 1971, should clearly set forth an exemption for dietary supplement products naturally containing ephedrine alkaloids by virtue of their ephedra content.

This exemption is necessary to avoid potential interpretation of the WHO'S recommendation as a restriction on access to these dietary supplement products.

In January, the State of Texas, acting through its Department of Health, acknowledged the *Importance* of preserving a consumer's right to purchase and use dietary supplements by abandoning previously proposed language that would have virtually halted all over-the-counter sales of dietary supplements containing naturally occurring ephedrine alkaloids in favor of newly proposed rules setting forth labelling requirements for such products without restricting consumers' access.

Last May, the state board of health approved proposed rules that would have required a prescription for most products containing ephedrine, including dietary supplements that contain ephedrine alkaloids . Those proposed rules were strongly opposed by manufacturers and marketers of dietary supplements.

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As a result, a work group of industry representatives and Texas Department of Health officials was formed to determined if a compromise to the prescription requirement could be achieved. The rules proposed by the group were approved by the Texas Board of Health in January. These new rules acknowledge the important distinction between products that contain the chemical ephedrine and those that contain naturally occurring ephedrine alkaloids derived from botanical sources. The ingredient sources of the alkaloids include raw botanicals and extracts from botanical sources. Ma huang, Ephedra, and Chinese Ephedra are common names used for botanical products, primarily from Ephedra sinica Stapf, E. equistestina Bunge, E. intermedia var. tibetica Stapf and E. distachya L., that are sources Of various ephedrine alkaloids.

Texas' action follows the ever-increasing trend that is making the distinction between botanical products and products containing chemical ephedrine by carving out specific exemptions regarding such products when increasing controls on ephedrine, Even FDA has acknowledged the distinction by separately addressing dietary supplements containing ephedrine alkaloids. Further, the proposed rule addressing these substances is another clear example of how competing interests with regard to these products can be addressed and reconciled.

Thus, the United States position on this proposal should include a request that the WHO recommendation be drafted in such a manner that it is clear that the restrictions imposed do not apply to dietary supplements containing ephedrine alkaloids from botanical sources. This position is not only consistent with the current stance on suoh products, but is essential to ensure continued access to botanical source ephedra dietary supplements.